

## Survey

# The Application of EU Competition Law in the Pharmaceutical Sector

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## I. Introduction

This survey article discusses the major EU competition law developments in the pharmaceutical sector from 1 January 2017 through 31 March 2018. Section II addresses cases on restrictions of competition from generic suppliers, including the UK Competition Appeal Tribunal's judgment in *GlaxoSmithKline* on patent settlements, the European Commission's annual patent settlement monitoring report and the French Competition Authority's decision in *Johnson & Johnson* involving an abuse of regulatory process and denigration. Section III covers the recent cases prosecuting excessive pricing, including *Aspen* and *Pfizer/Flynn* in the United Kingdom. Section IV discusses the EU Court of Justice's judgment in *Roche/Novartis* concerning licensing agreements. Section V addresses recent decisions, judgments, and regulations in EU Member States on the ongoing issue of parallel trade. Finally, Section VI covers the opening of new national pharmaceutical sector inquiries.

## II. Restriction of competition on generic suppliers

### A. Reverse-payment patent settlements

#### 1. Introduction

While the last year has not seen any new decisions against pharmaceutical companies involving reverse-payment patent settlements, the existing cases have continued to wind their way through the courts, with the principal development arising in the UK *GlaxoSmithKline* case, in which the UK Competition Appeal Tribunal (CAT) has issued a judgment that refers questions of EU law to the EU Court of Justice. This referral, together with the separate appeal in *Lundbeck*, gives the Court of Justice an opportunity to resolve the long-standing debate on how such patent settlements should be assessed under EU competition law.

## Key Points

- Competitive restrictions on generics remain an area of focus, as reverse-payment patent settlement cases work their way through the EU and UK courts and a new denigration decision was issued against Johnson & Johnson in France.
- Excessive pricing of off-patent medicines is garnering increased attention at both EU and national level (the European Commission has opened its first pharmaceutical excessive pricing investigation against Aspen).
- While there have been new developments in anti-competitive licensing agreements, notably the European Court of Justice's ruling in *Roche/Novartis*, the area of parallel trade remains relatively quiet.

As background, certain reverse-payment patent settlements have come under scrutiny by European competition authorities under the theory that innovative pharmaceutical companies may use such settlements to unfairly delay or prevent generic market entry to the detriment of the consumer. The Commission issued decisions in these types of cases in *Lundbeck* in 2013 and in *Servier* in 2014, while the UK Competition and Markets Authority (CMA) issued its decision in *GlaxoSmithKline* in 2016. All of these decisions were immediately appealed, with *Lundbeck* in the lead and now before the Court of Justice, following an earlier judgment by the General Court upholding the Commission's decision. *Servier* is on appeal to the General Court, but has now been leapfrogged by *GlaxoSmithKline*, which is already before the Court of Justice due to the referral from the UK CAT. *GlaxoSmithKline* will thus take on increased importance in the development of the law on reverse-payment patent settlements, as it will be the first case in which

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two parties in the *Lundbeck* case, which is currently on appeal to the Court of Justice. The views expressed in this article are their own and should not be attributed to their clients.

the Court of Justice must address whether such settlements constitute an abuse of dominance or a restriction of competition 'by effect', issues which did not arise in *Lundbeck*.

We briefly recall the details of *Lundbeck* and *Servier*, and, in the next section, discuss the recent referral to the Court of Justice in *GlaxoSmithKline*.

*Lundbeck*. In September 2016, the General Court issued its judgments in the first-ever case on reverse-payment patent settlements in the pharmaceutical sector, upholding the Commission's decision against *Lundbeck*, the Danish pharmaceutical company, and the generic manufacturers *Alpharma*, *Merck KGaA/Generics UK*, *Arrow* and *Ranbaxy*.<sup>1</sup> As noted, these judgments are currently on appeal to the Court of Justice.<sup>2</sup>

While the circumstances and agreements for each settlement were different, and thus each judgment by the General Court – one for each of *Lundbeck* and the generics – is different, there are certain common core issues that are important from the standpoint of the development of competition law and policy. These appeals offer the Court of Justice a superb occasion to provide guidance on how to strike the correct balance between intellectual property and competition law.

The arguments on appeal are likely to centre on the role of the patent in both the analysis of potential competition and whether there is a restriction by object. The General Court's judgment seems to endorse a low threshold for the existence of potential competition as it seems sufficient that the generic has taken steps to enter the market. The existence of a patent would rarely, if ever, be viewed as excluding potential competition as the generic would always have at least some chance of winning in any eventual patent litigation. Likewise, the General Court seems to gloss over the patent in concluding that there is a restriction of competition by object. This conclusion seems questionable as it necessarily assumes that the originator would have little chance of excluding the generic in the absence of the agreement. *Lundbeck* and the generics will undoubtedly

seek to convince the Court of Justice that the General Court failed to analyse properly the role of the patent in reaching its conclusions.

This case also offers the Court of Justice an unusually good opportunity to clarify the scope and meaning of a 'by object' restriction. As it seemed to take the combination of a sector inquiry, a 10-year investigation and a 466-page decision for the Commission to reach the conclusion that the settlement agreements at issue in this case infringed Article 101, it would seem at least questionable whether they should be treated as 'by object' restrictions that 'by their very nature' are restrictive of competition, particularly in light of the Court of Justice's ruling in *Cartes Bancaires*,<sup>3</sup> in which it seemed to narrow the scope of the 'by object' restriction. Moreover, it would seem at least debatable whether the agreements had the kind of high likelihood of restricting competition that characterises restrictions by object given that the available evidence seemed to suggest that *Lundbeck* had a reasonable chance (40–50 per cent) of winning the patent litigation.

*Servier*. In 2014, the Commission imposed a fine of €331 million on *Servier*, the French pharmaceutical company, and fines totalling €96 million on five generic manufacturers – *Unichem*, *Matrix* (now *Mylan*), *Teva*, *Krka*, and *Lupin*.<sup>4</sup> This decision is currently on appeal to the General Court.<sup>5</sup>

The Commission's decision in *Servier* differs from the *Lundbeck* decision in two key respects. First, while the Commission only analysed the settlement agreements under a 'by object' test in *Lundbeck*, it hedged its bets and also applied an 'effects' test in *Servier*. Second, the Commission found that, in addition to entering into agreements that restricted competition in violation of Article 101, *Servier*'s conduct constituted an abuse of its dominant position in violation of Article 102.

## 2. GlaxoSmithKline

On 8 March 2018, the UK's CAT issued its judgment in *GlaxoSmithKline*<sup>6</sup> concerning appeals against the

1 Case T-472/13, *Lundbeck v. Commission*, Case T-471/13, *Xellia Pharmaceuticals and Alpharma v. Commission*, Case T-470/13, *Merck v. Commission*, Case T-469/13, *Generics (UK) v. Commission*, Case T-467/13, *Arrow Group and Arrow Generics v. Commission* and Case T-460/13, *Sun Pharmaceutical Industries and Ranbaxy (UK) v. Commission* (8 September 2016).

2 Case C-591/16, *Lundbeck v. Commission*; Case C-611/16, *Xellia Pharmaceuticals and Alpharma v. Commission*; Case C-614/16, *Merck v. Commission*; Case C-588/16, *Generics (UK) v. Commission*; Case C-601/16, *Arrow Group and Arrow Generics v. Commission*; and Case C-586/16, *Sun Pharmaceutical Industries and Ranbaxy (UK) v. Commission*.

3 Case C-67/13P, *Groupement des Cartes Bancaires v. European Commission* (11 Sept. 2014) (not yet reported).

4 Case AT.39612, *Servier*, Decision of 9 July 2014.

5 See Cases T-705/14, *Unichem Laboratories v Commission*, T-701/14 *Niche Generics v Commission*, T-691/14, *Servier and Others v Commission*, T-684/14, *Krka v Commission*, T-682/14, *Mylan Laboratories and Mylan v Commission*, T-680/14, *Lupin v Commission*, T-679/14, *Teva UK and Others v Commission*, T-677/14, *Biogaran v Commission*.

6 *Generics (UK) Limited, GlaxoSmithKline PLC, Xellia Pharmaceuticals APS and Alpharma LLC, Actavis UK Limited and Merck KGaA v. Competition and Markets Authority*, Case Nos. 1251-1255/1/12/16, [2018] CAT 4 ('GSK'). See also the CAT's Order for Reference for a Preliminary Ruling (27 March 2017).

CMA's decision imposing fines totalling £44.99 million on GlaxoSmithKline (GSK) and generic manufacturers for entering into reverse-payment patent settlements in connection with GSK's blockbuster anti-depressant drug Seroxat (paroxetine).<sup>7</sup>

In 2001, a number of generic competitors sought to enter the UK market with a generic version of Seroxat, which was one of the world's most popular anti-depressants and one of GSK's best-selling products. GSK initially launched litigation against the generics, alleging that the generic products were infringing its patents, but, prior to trial, the parties entered into settlements. Under the agreements, GSK agreed to supply the generics with product and to make payments and other value transfers totalling over £50 million. In turn, the generics agreed to refrain from entering the UK market for paroxetine from 2002 to 2004.

The CMA held that these settlement agreements protected GSK from the competition it would have otherwise faced from the threat of entry by independent generic competitors, and deprived the National Health Service of the price reductions that normally result from generic competition. Like the European Commission in *Servier*, the CMA relied on both the 'by object' and 'by effect' theories in finding an infringement of Article 101. In addition, the CMA found that GSK had abused its dominant position in violation of Article 102 as the payments to the generics meant that GSK took actions that were different from those characteristic of 'normal competition.'

On appeal, the UK CAT in March 2018 issued a judgment rejecting grounds of challenge raised by GSK and the generics concerning the parties' rights of defense, the attribution of liability and whether the agreements qualified for UK and EU block exemptions (safe harbours). However, on the key issues arising in the case, the CAT decided to stay the proceedings and refer questions to the EU Court of Justice. As the CMA's decision raised many of the same issues as the European Commission's decisions that are on appeal to the European Courts in *Lundbeck* and *Servier*, the CAT hopes to avoid arguments in the UK courts concerning the application of the eventual judgments in the EU cases to the UK case.<sup>8</sup> The CAT used the opportunity to set out its provisional views on the questions, which is relatively rare in references from national courts. However, as the CAT is bound by *Lundbeck*, it did not depart from the approach of the General Court in *Lundbeck* on the issues of potential competition and

restriction by object. With regard to the other issues that were not addressed in *Lundbeck* – restriction by effect, market definition and dominance – the CAT had more freedom to pursue an independent line of reasoning and, as discussed below, disagreed with the CMA on certain points.

The key issues referred to the Court of Justice are as follows:

*Potential competition.* The CAT asked whether an originator and a generic are potential competitors where there is a bona fide dispute as to validity and infringement. The CAT found that the generics in that case were clearly prepared and willing to enter the market and did not believe that the entry of interim injunctions against them in the context of UK litigation meant that they were no longer potential competitors. The CAT also emphasised that the General Court's judgment in *Lundbeck* held that the existence of a patent did not mean that the generics could not be considered as potential competitors as they could enter the market, albeit subject to the risk of patent litigation.

*Restriction by object.* The CAT also asked whether a settlement agreement involving a reverse payment constitutes a restriction by object. The CAT discussed this issue at length in its judgment. In contrast to *Lundbeck*, *GlaxoSmithKline* involved ancillary supply agreements with the generics that arguably produced benefits during the period covered by the settlement agreements. It will be interesting to see to what extent this difference could affect the analysis of the possible restriction by object. With regard to the issue of whether the strength of the patent would affect the characterisation of an agreement as a restriction by object, the CMA seemed slightly uncomfortable with using the 'by object' approach where the evidence showed that the originator had an 80 per cent chance of winning,<sup>9</sup> but considered that it would not be practical for a competition authority to engage in an analysis of the strength of the patent.<sup>10</sup>

*Restriction by effect.* The CAT asked whether a restriction of competition by effect required a finding that the generic company would probably have succeeded in the patent litigation or that the parties would probably have entered into a less restrictive settlement. On the issue of restriction by effect, the CAT appears to disagree with the CMA on the grounds that the CMA failed to show that it was more likely than not that the counterfactual – i.e. what would have happened in the absence of a settlement – would have been more competitive. The CAT noted that it was impossible to say

7 *Paroxetine*, Case CE-9531/11 (12 Feb. 2016)

8 *GSK*, para. 87.

9 *GSK*, para. 262.

10 *GSK*, para. 324.

that the generic would have won if there had been no settlement and litigation had continued to judgment.<sup>11</sup> Likewise, it found that whether the parties would have been likely to enter into a less restrictive settlement in the absence was a matter for 'pure speculation'.<sup>12</sup> While the CAT admitted that a generic victory in litigation or a less restrictive settlement were possible, this was not sufficient without transforming a test of reasonable likelihood or probability of effects into 'a test of the probability of a possibility'.<sup>13</sup>

*Market definition.* The CAT asked whether the relevant market should include the generics even though they had not yet entered the market. The CAT's judgment contains an interesting discussion of the issue of relevant market definition in a market that is on the verge of going generic. The CAT found that the relevant market would consist of paroxetine and its generic versions, but would not include anti-depressants that competed with paroxetine prior to generic entry. The basic reasoning was that generics had a much greater effect on the price of paroxetine than did other products. As this same issue is raised in the *Servier* appeal that would be likely to eventually reach the Court of Justice, the CAT believed it would be appropriate to go ahead and raise the issue with the Court of Justice.

*Dominance.* The CAT asked whether entering into the settlement agreements would also constitute an abuse of a dominant position, particularly if it is part of a broader strategy of entering into such agreements to delay generic entry. As *Lundbeck* did not involve an Article 102 violation and *Servier* is not yet before the Court of Justice, this will be the first time that the Court of Justice will have an opportunity to address this question.

### 3. Teva

On 17 July 2017, the Commission issued a Statement of Objections in which it alleged that an agreement concluded with Cephalon in the settlement of UK and US litigation, in which Teva agreed not to market a generic for Cephalon's sleep disorder drug, modafinil, violated Article 101. Cephalon held patents for both the modafinil compound and its manufacture. When Cephalon's patents on the compound expired, Teva had briefly entered the UK market with a generic product. Pursuant to a global settlement with Cephalon for alleged infringement of its processing patents, Teva agreed not to sell its generic product in the EEA until 2012, in exchange for cash payments and other agreements. Teva acquired

Cephalon in 2011, at which time the Commission opened a formal investigation. The Commission has found that this settlement constituted a pay-for-delay agreement to reduce competition by delaying entry for generic modafinil in Europe. This patent settlement was also the subject of an FTC antitrust investigation, which the parties settled in 2015.

### 4. Patent Settlement Monitoring Report

The Commission has issued its Eighth Monitoring Report<sup>14</sup> as part of its ongoing review of patent settlements in the pharmaceutical sector. Each year, originator and generic companies submit copies of all patent settlement agreements covering EU/EEA markets concluded during the previous calendar year together with related agreements. This Report, which adopts the same language and structure as in previous years, discusses the main categories of settlements, and then provides an overview of the responses received from companies and an analysis of the principal characteristics of the settlements falling under each category. It classifies certain settlements under Categories A and B.I as unproblematic, which is unsurprising as Category A agreements do not restrict generic entry at all, while Category B.I agreements involve no value transfer whatsoever to the generic entrant i.e. the latter agrees to enter after patent expiry. The report labels the remaining Category B.II agreements – those which involve a value transfer from the originator and no immediate market entry by the generic – as most likely to raise competition concerns.

Like earlier reports, it is debatable whether this Report provides any meaningful insight for competition authorities or companies on the issue of patent settlements. While the Report offers statistics concerning the patent settlements concluded over the past year, these provide little meaningful data. For example, the Eighth Report indicates a slight drop in the number of settlements without indicating how this figure compares to the number of cases litigated, rendering the statistic meaningless. Moreover, by classifying settlements in terms of their perceived degree of competition law risk, the Report fails to provide useful guidance, but arguably creates a chilling effect on the conclusion of settlements that might be pro-competitive, such as those providing for early generic entry. Agreements falling into the benign categories – Categories A and B.I. – are arguably not truly settlements at all, insofar as one party or the other has capitulated entirely. Some settlements falling

<sup>11</sup> GSK, para. 333.

<sup>12</sup> GSK, para. 334.

<sup>13</sup> GSK, para. 348.

<sup>14</sup> European Commission, 8<sup>th</sup> Report on the Monitoring of Patent Settlements (9 March 2018).



under the higher-risk Category B.II may in fact be pro-competitive by allowing for early generic entry. Although the Commission has acknowledged that pure early entry settlements are ‘not likely to attract the highest degree of antitrust scrutiny,’<sup>15</sup> it has failed to state more clearly that these agreements are, in fact, unlikely to raise competition law concerns. This is one example of the Commission’s general lack of concrete guidance on the issue of patent settlements. Given its experience in the *Lundbeck* and *Servier* cases and now eight years monitoring such agreements, it would appear that the Commission has enough expertise on the subject to provide more substance to the limited guidance found in its monitoring reports.

## B. Abuse of regulatory process and denigration

European competition authorities have historically imposed high fines on innovative pharmaceutical companies for abusing a dominant position through strategies to keep their prices high by delaying generic entry or discouraging prescribing physicians, pharmacists and consumers from choosing cheaper, generic versions of their products. On 20 December 2017, the French Competition Authority (FCA) issued a decision<sup>16</sup> imposing a €25 million fine on Janssen-Cilag and its parent company, Johnson & Johnson, for abusing its dominant position in the market for transdermal fentanyl patches. The FCA found that Janssen-Cilag’s abusive conduct consisted of two related strategies to hinder entry and uptake of generics for its Durogesic patch: (1) unfounded intervention in the national marketing authorisation approval process, and (2) a widespread denigration campaign to raise doubts about generics’ safety and efficacy.

In October 2007, following a close evaluation by the European Medicines Agency (EMA), the European Commission adopted a decision requiring certain EU Member States, including France, to provide a national marketing authorisation for Ratiopharm’s generic transdermal fentanyl patch in mutual recognition of an authorisation already granted in Germany. Nevertheless, it took the French medical authority (AFSSAPS) until November 2008 to finally grant generic status to Ratiopharm’s product. The FCA concluded that this delay was the result of Janssen-Cilag’s repeated and unwarranted interventions. Specifically, through multiple letters, presentations and meetings, Janssen-Cilag conveyed to AFSSAPS its doubts about the bioequivalence of Ratiopharm’s product, which

contained a different dose of the active ingredient, and potential patient risks of ‘destabilization’ or ‘overdose’ arising from any substitution for its Durogesic patches. This prompted AFSSAPS to initially refuse generic status, and then to ultimately grant it after many months’ delay with the warning that certain vulnerable patient groups should be monitored actively when switching between fentanyl patches produced by different manufacturers. As a result of this interference, Ratiopharm’s entry into the generic market was delayed for 11 months while it responded to concerns from AFSSAPS.

The FCA concluded that Janssen-Cilag’s intervention was an abuse of its dominant position. In so doing, it distinguished two standards according to which this conduct could be judged: the higher bar of vexatious litigation established under *ITT Promedia*,<sup>17</sup> and the standard of misleading information set out in *AstraZeneca*<sup>18</sup> and *Roche/Novartis*.<sup>19</sup> The FCA rejected the application of the *ITT Promedia* standard, finding it applied only to judicial proceedings – in which a complainant has a legally-protected right to appear and thus enjoys a higher level of protection – and not to interventions before an administrative body in which the complainant holds no such right. The FCA concluded that, under the *AstraZeneca* misleading information standard, Janssen-Cilag’s intervention was abusive because, given AFSSAPS’ lack of discretion in light of the prior Commission decision granting Ratiopharm’s product generic status, its submissions were ‘alarmist,’ ‘legally unfounded and intended to convince the public authority to make a decision it should not take.’<sup>20</sup> In short, Janssen-Cilag knew the EMA had already considered its concerns, and that the French authority was required to approve the product, but it nonetheless intervened.

The FCA’s finding that Janssen-Cilag engaged in abusive conduct by intervening in the administrative approval process is troubling. While the lower *AstraZeneca* standard on misleading information might logically apply if the content of Janssen-Cilag’s submissions to an administrative agency such as the AFSSAPS were demonstrably misleading or incorrect, it would not seem appropriate to rely on it to assess the kind of abuse -of -regulatory -process issue alleged by the FCA. Rather than alleging misleading or incorrect statements, the FCA’s case appears to be based largely on allegations that Janssen-Cilag made submissions to the AFSSAPS while knowing that the issues it raised had already been addressed at EU-level and that AFSSAPS had no choice but to approve the product.

15 8<sup>th</sup> Report on the Monitoring of Patent Settlements, para. 12.

16 Decision 17-D-25 (20 December 2017).

17 Case T-119/09, *ITT Promedia v Commission* (17 July 1998).

18 Case C-457/10P, *AstraZeneca v Commission* (6 December 2012).

19 See Part V.A., below.

20 Decision 17-D-25 (20 December 2017), paras. 513, 517.

Instead of the misleading standard applied by the FCA, the allegations against Janssen-Cilag would seem best assessed under the second legal standard established in *AstraZeneca*, in the context of the withdrawal of AstraZeneca's marketing authorisation. This standard is directly applicable to such allegations of abuse of regulatory process, and establishes that a dominant company 'cannot [...] use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.'<sup>21</sup> Applying this standard, the relevant question would be whether Janssen-Cilag expression of its concerns about generics to AFSSAPS was objectively justified.

Rather than applying this logical, existing legal standard to the actions of Janssen-Cilag, and thereby conducting a thorough analysis of the circumstances in which a dominant pharmaceutical company is justified in expressing safety concerns to a regulatory authority, the FCA instead applied the irrelevant 'misleading' standard, which is not fit for purpose and results in very muddled logic in the decision. Indeed, one key question not adequately addressed is the contradiction between the FCA's allegations that Janssen-Cilag should have known that it should not submit its safety concerns to AFSSAPS (even if correct and not misleading), while the AFSSAPS itself appeared to believe such submissions were relevant, and therefore spent months examining the dossier before granting Ratiopharm's product generic status. The FCA is thus second guessing the regulatory authority concerning what information is allowable and relevant to the regulatory authority's assessment, and thereby creating uncertainty concerning what information companies may submit. The obvious danger of this decision is that, if companies have to worry about being attacked on competition grounds for raising health and safety concerns in the context of a regulatory process that is not crystal clear, this could make them reluctant to even raise such concerns at all.

The FCA also found that Janssen-Cilag conducted a subsequent denigration strategy to discourage physicians from prescribing generic patches as a substitute for its Durogesic patch. Janssen-Cilag trained representatives interacting with medical professionals to emphasise the key message that switching patients from Durogesic to a generic would represent a risk to patients. In particular, it provided a model set of

responses to questions raised about the suitability of generic patches, which emphasised that generic versions did not have the same composition, size or quantity of fentanyl, which could lead to added variability in the concentration of the drug in the bloodstream and increased patient risk. Janssen-Cilag also sent letters to pharmacists, physicians and medical press outlets reiterating the AFSSAPS's warning issued with the approval of Ratiopharm's generic patch. These letters, however, mischaracterized the warning in several ways: they implied incorrectly that the warning related only to the risk of switching patients from Durogesic to a generic, whereas the warning applied to a switch between any products; they failed to mention that such switching risks could be effectively eliminated by proper medical surveillance; and they placed undue importance on the fact that this was the first time the AFSSAPS had issued a warning alongside the marketing authorisation for a generic, as prior to 2008, French law had not allowed for such warnings to be issued. Other features of the denigration campaign included pop-up warnings that would appear when pharmacists searched for Durogesic in their computer systems and telephone conference calls targeting pharmacists.

The FCA's review of Janssen-Cilag's internal documents supported the conclusion that both the intervention in the AFSSAPS procedure and the subsequent denigration campaign were part of a broad strategy to discourage generic entry. In particular, the FCA found that this strategy dated from the formation of an internal 'ANTI-Generics for Durogesic Team' at the time the drug's patent protection expired in 2005. These documents also revealed that the company had analysed the effect on Durogesic's revenues that could be achieved if significant generic uptake could be delayed from early 2008 to 2009. The FCA concluded that Janssen-Cilag's intervention and 'smear' campaign had precisely this effect, justifying the size of the fine imposed.

### III. Excessive pricing

#### A. Policy considerations

At both EU and national level, competition authorities are showing an increasing willingness to pursue excessive pricing cases against companies marketing off-patent medications, particularly where there is a drastic increase in price. In such cases, the authority can easily judge the new price as excessive with reference to the prices previously charged. Moreover, as drugs are

21 Case C-457/10P, *AstraZeneca v Commission* (6 December 2012), para 134.

expected to drop in price once they are off-patent, price increases are more likely to be viewed with suspicion, particularly as the drug's originator has presumably already recouped its R&D costs.

In 2017, the European Commission appears to have abandoned its former reluctance to engage in excessive pricing investigations. Following on the heels of numerous cases pursued by national competition authorities in 2016, including *Aspen*, *Pfizer/Flynn* and *Actavis*, the Commission has now shown a clear intention to address excessive pricing for off-patent drugs. In a speech on 27 January 2017, Commissioner Vestager emphasised that drug prices needed to reward innovation while remaining affordable to the consumer, and that 'competition enforcement can help get that balance right.'<sup>22</sup> Later in the year, the Commission launched its first excessive pricing probe against Aspen. This could be the first case in what may become a new area of scrutiny for the Commission in the pharmaceutical industry now that its interest in patent settlements appears to be winding down.

It remains unclear whether the EU or national authorities will be willing to extend their investigations to include excessive prices for innovative products. Chris Fonteijn, Chairman of the Dutch competition authority (ACM), recently co-authored a paper highlighting the need to curb originator companies' abuse of dominance though misuse of IP protection mechanisms and excessive pricing.<sup>23</sup> In particular, the paper notes that, when price constraints are too weak, originator companies can set prices far above the level needed to reward innovation. It recommends that, rather than shielding innovative companies entirely, welfare-enhancing concerns related to innovation should be just one factor among others taken into account in the legal test for excessive pricing. The ACM has indicated that a review of pharmaceutical prices will be a priority in 2018,<sup>24</sup> therefore the Netherlands may provide an early test case for the prosecution of innovative drug companies for excessive pricing.

## B. Aspen (EU)

The European Commission opened a formal investigation into Aspen's pricing practices for five life-saving cancer

medications on 15 May 2017.<sup>25</sup> The announcement follows the Italian and Spanish competition authorities' decisions to investigate Aspen for the same behaviour. The Commission's investigation covers the entire EEA, except Italy, which had already adopted an infringement decision in 2016, and led the Spanish authority to close its own investigation in July 2017.<sup>26</sup>

Aspen had acquired the cancer drugs at issue from GSK once their patent protection had expired. The Commission will investigate allegations that Aspen had engaged in 'price gouging' by raising its prices on these medicines by several hundred per cent. It will also examine whether Aspen used abusive tactics in negotiations with national authorities or hindered parallel trade by threatening to withdraw products from the national market, reducing direct medicine supply or implementing EEA-wide stock allocation strategies with the cooperation of national wholesalers.

In opening the investigation, the EU signalled its intention to prosecute companies that engage in excessive pricing practices for off-patent drugs. Commissioner Vestager indicated that '[c]ompanies should be rewarded for producing these pharmaceuticals to ensure that they keep making them into the future. But when the price of a drug suddenly goes up by several hundred per cent, this is something the Commission may look at.'

## C. Aspen (Italy)

On 26 July 2017 the Regional Court of Lazio rejected Aspen's appeal of the Italian competition authority's (ICA) decision<sup>27</sup> to impose a €5.2 million fine on Aspen for abusing its dominant position by charging excessive prices for the supply of off-patent cancer drugs it had acquired from GSK. By applying the two-step test developed by the Court of Justice in *United Brands*, the ICA had concluded that Aspen had increased its prices 300–1,500 per cent over those previously charged by GSK.

The Court dismissed Aspen's procedural and substantive arguments. In particular, the Court upheld the ICA's application of the *United Brands* test. First, it found that the ICA had correctly determined that Aspen's prices were excessive in comparison with its

22 Commissioner Vestager, 'Restoring trust in our economy,' Speech to the Association of the Danish Pharmaceutical Industry New Year Conference, Copenhagen (27 January 2017).

23 Chris Fonteijn, Ilan Akker and Wolf Sauter, 'Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse,' ACM Working Paper (8 March 2018).

24 Authority for Consumers & Markets, Press Release, 'ACM's key priorities for 2018 and 2019: digital economy, green energy, prescription drug prices, and ports (13 February 2018).

25 European Commission, Press Release, Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines (15 May 2017) ([http://europa.eu/rapid/press-release\\_IP-17-1323\\_en.htm](http://europa.eu/rapid/press-release_IP-17-1323_en.htm)).

26 Spanish Competition Authority, Resolution S/DC/0601/17 (20 July 2017).

27 Italian Competition Authority, Case A-480 (29 Sept. 2016).

costs (assessed based on the gross margin of contribution and on a cost-plus basis). The second part of the *United Brands* test examines whether the excessive prices charged are unfair, and therefore an abuse of dominance. The Court sustained the ICA's decision that Aspen could not provide any justification for the price increase, rejecting Aspen's arguments that consumers' willingness-to-pay should have been considered a relevant factor, given the life-saving nature of the products.

The Court also affirmed that the ICA was correct in examining Aspen's pricing negotiations with the Italian Medicines Agency (AIFA) as part of its determination of abuse of dominance. The ICA had concluded that Aspen had used an aggressive negotiating strategy, leveraging its market position, to force AIFA to accept its excessive prices. Aspen had first demanded that the cancer drugs be reclassified as non-reimbursable. When this approach failed, it threatened to withdraw the products from the market unless the prices were substantially increased. The Court clarified that, while Aspen did not violate the regulatory rules themselves, Aspen's interactions with AIFA consisted of a 'conscious use of the negotiating tool' to abuse its dominant position. Specifically, Aspen's negotiating strategy was 'expressive of the ultimate aim of taking advantage of its market power ... to impose unfair prices'. Pharmaceutical companies will therefore need to take into account the possible competition law risk in determining how aggressive a stance to take in pricing negotiations.

#### D. Pfizer/Flynn

Pfizer and Flynn Pharma have appealed the CMA's decision of 7 December 2016 in which the CMA had imposed a £84.2 million fine on Pfizer and £5.2 million fine on Flynn Pharma for allegedly charging excessive and unfair prices for phenytoin sodium capsules.<sup>28</sup> The appeal is pending before the CAT.

#### E. Actavis, Intas, Accord

On 16 December 2016, the CMA issued an initial Statement of Objections against Actavis<sup>29</sup> in which it

concluded that the company breached competition law by charging excessive prices for its hydrocortisone tablets. Actavis had raised the prices of these off-patent life-saving products by 9,500–12,000 per cent compared to prices offered by a company offering a branded version of the drug in 2008. The CMA issued a second Statement of Objections on 9 August 2017, maintaining the charges against Actavis and naming Intas and Accord, who purchased the company in January 2017, as jointly and severally liable.

#### F. Concordia

The CMA issued a Statement of Objections against Concordia on 21 November 2017 finding that the company had abused its dominant position by charging the NHS excessive and unfair prices for liothyronine tablets.<sup>30</sup> Liothyronine tablets are prescribed for hypothyroidism, and while they are not the primary treatment for the condition, they are the only suitable treatment for certain patients. The CMA found that since the drug had been de-branded in 2007, its price had risen by almost 6,000 per cent despite largely stable production costs. The CMA noted that, until 2017, Concordia had been the only available supplier and therefore the NHS had no choice but to purchase liothyronine tablets at these elevated prices. On 15 February 2018, the CMA announced that it had stopped its investigation of Concordia's pricing of fucidic acid eye drops to focus its attention instead on its liothyronine tablet pricing.

#### G. CD Pharma

On 31 January 2018, the Danish Competition Council ruled that CD Pharma, a pharmaceutical distributor, had abused its dominant position by charging excessive prices for Syntocin, a drug containing oxytocin administered in connection with childbirth.<sup>31</sup> Syntocin has been available on the market since the 1950s and has long been off-patent. CD Pharma was found to hold a dominant position on the Danish market due to an exclusive distribution arrangement with the drug's producer. According to the Council, CD Pharma increased its

28 Pfizer, Press Release, *Pfizer statement on Competition and Markets Authority's infringement decision* (7 December 2016) (<http://www.pfizer.co.uk/latest-news/2016-12-07-pfizer-statement-competition-and-markets-authority%E2%80%99s-infringement-decision>); Flynn Pharma, Press Release, *CMA issue infringement Decision against Flynn* (7 December 2016) (<http://www.flynnpharma.com/about-us/news/cma-issues-infringement-decision-against-flynn>).

29 Competition and Markets Authority, Press Release, *Pharmaceutical company accused of overcharging NHS* (16 December 2016) (<https://www.gov.uk/government/news/pharmaceutical-company-accused-of-overcharging-nhs>).

30 Competition and Markets Authority, Press Release, *Drug company accused of abusing its position to overcharge the NHS* (21 November 2017) (<https://www.gov.uk/government/news/drug-company-accused-of-abusing-its-position-to-overcharge-the-nhs>).

31 Danish Competition Council, Press Release, *CD Pharma has abused its dominant position by increasing their price by 2,000 per cent* (31 January 2018) ([https://www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/?utm\\_source=POLITICO.EU&utm\\_campaign=d6fa8ed9d6-EMAIL\\_CAMPAIGN\\_2018\\_01\\_31&utm\\_medium=email&utm\\_term=0\\_10959edeb5-d6fa8ed9d6-189777977](https://www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/?utm_source=POLITICO.EU&utm_campaign=d6fa8ed9d6-EMAIL_CAMPAIGN_2018_01_31&utm_medium=email&utm_term=0_10959edeb5-d6fa8ed9d6-189777977)).



price for the drug by 2,000 per cent between April and October 2014. The company was not able to explain the sudden hike in its prices by any research and development activities or any increase in production or distribution costs.

The Council's analysis in this case took into consideration the role of parallel trade. The complaining hospital buyer had entered into a supply agreement with Orifarm, a parallel importer that competed with CD Pharma. When supply from that importer was interrupted, the distributor had to buy the residual amount from CD Pharma at a much higher price. As part of its determination that CD Pharma's price was excessive, the Council interestingly compared it to the price the hospital had originally negotiated with Orifarm. The Council also noted that CD Pharma's abusive conduct might have the effect of restricting parallel trade. Specifically, suppliers entering into contracts that oblige them to cover the loss in case of delivery failure are likely to take into account the risk of compensation claims from buyers who must source products elsewhere at a higher price. This risk would fall more heavily on parallel importers, who are generally less able to secure a stable supply of products. Consequently, as a result of CD Pharma's abusive pricing, bids from parallel importers might become less competitive, with repercussions on hospitals' procurement of medicines. As an indication of the seriousness of the abuse, the Council decided to submit the matter to the Danish State Prosecutor for Serious Economic and International Crime.

## IV. Exclusionary pricing

European competition authorities continue to prosecute instances of exclusionary pricing, whereby a dominant pharmaceutical company sets prices at which competitors are unable to enter or compete effectively on the relevant market, ultimately reducing the choices available to consumers and national health agencies.

### A. MSD

On 23 May 2017, the CMA issued a Statement of Objections alleging that MSD has breached UK and EU competition law by implementing an abusive discount scheme in relation to the supply of Remicade (infliximab) to the NHS.<sup>32</sup> Specifically, the CMA indicated that MSD's discounts to the NHS were an abuse of its

dominant position insofar as they were likely to restrict competition from new biosimilar versions of infliximab entering the UK market.

### B. Roche (Romania)

On 7 December 2012, the Romanian Competition Council launched two inquiries investigating whether Roche abused its dominant position in the market for oncological products in Romania. In the first probe, the Council is examining whether Roche is applying a discriminatory pricing structure to favour direct-to-hospital sales. Roche Romania SRL together with one of its wholesale distributors are allegedly offering wholesale prices that are significantly higher than those the Romanian affiliate offered in tender procedures for the supply of hospitals.

In the second investigation, the Council is investigating whether Roche may be unfairly excluding generics for its innovative cancer drug Tarceva (erlotinib) from the market through the use of marketing and promotional techniques. The probe stems from the results of a pharmaceutical sector inquiry concluded in 2016, in which the Council found that cheaper, generic medications were unable to gain a significant share of the Romanian market. The sector inquiry determined that, although prescriptions specifying a branded drug were warranted only in exceptional cases, 57 per cent of patients nonetheless requested a non-generic upon the advice of their physician as the result of promotional efforts by innovative drug companies.

## V. Licensing agreements – coordination among competing suppliers

### A. Roche/Novartis

On 23 January 2018, the EU Court of Justice issued a preliminary ruling on questions referred by the Italian Council of State in *Roche/Novartis*.<sup>33</sup> This case arose from appeals against the February 2014 decision of the Italian competition authority imposing fines of €92 million on Novartis and €90.6 million on Roche for allegedly attempting to restrict competition between two products, Avastin and Lucentis. The Regional Court of Lazio upheld the authority's decision on 5 November 2014, and its judgment was appealed to the Council of

32 <https://www.gov.uk/government/news/cma-issues-provisional-decision-in-relation-to-drug-firms-pricing>

33 Case C-179/16, *F. Hoffmann-La Roche AG, La Roche SpA, Novartis AG and Novartis Farma SpA v Autorita Garante della Concorrenza e del Mercato* (23 Jan. 2018).

State, which referred questions on the interpretation of EU law to the Court of Justice.

The case involves two drugs developed by Genentech that came out of a research programme aimed at finding ways to stop the process of blood-vessel formation called angiogenesis, which feeds tumour growth in cancer patients and also causes certain eye diseases. The first drug to be developed was Avastin, which was designed to treat cancer. A couple of years later, a derivative of the main compound in Avastin was developed into Lucentis, a drug to treat eye disease. Before Lucentis came onto the market, doctors used Avastin on an 'off-label' basis to treat eye disease as well. In other words, even though Avastin was only approved for the treatment of cancer, doctors also prescribed it for treating the eye disease, an unregistered or 'off-label' use.

As Genentech did not have a sales network in Europe, it licensed the products out – Avastin to its parent company, Roche, and Lucentis to Novartis. Avastin was sold at a maximum price of €81 per injection in Italy, while Lucentis was much more expensive – it started at a price €1700 per injection, which was later lowered to €900. Before Lucentis was launched on the Italian market, Avastin was widely prescribed by doctors on an 'off-label' basis to treat eye disease. The Italian regulatory regime allowed such off-label use of a drug if there was no registered treatment available. Once Lucentis was launched on the Italian market, the off-label use of Avastin for eye disease was no longer reimbursed because there was now a drug available that was registered for the treatment of eye disease. The switch from Avastin to Lucentis for the treatment of eye disease led to a dramatic increase in the cost of treating the eye disease, which generated complaints by private healthcare clinics and the Italian Ophthalmological Society, which eventually prompted the competition authority to open its investigation.

After a year-long investigation, the competition authority concluded that Roche and Novartis had colluded to prevent Avastin from competing with Lucentis. While Novartis naturally had an incentive to prevent the use of Avastin for the treatment of eye disease, Roche had a similar incentive because, as Genentech's parent company, it stood to gain more from the royalties paid to Genentech by Novartis for sales of Lucentis than from the profits generated by sales of Avastin.

According to the decision, the parties carried out a campaign aimed at artificially differentiating Avastin and Lucentis by raising safety concerns about the off-label use of Avastin to treat eye disease. More

specifically, Roche had sought a change to the label of Avastin in order to highlight its risks if used to treat eye disease, and the two companies sought to downplay independent studies showing that the two drugs were equivalent. The authority found numerous internal documents discussing this strategy as well as communications between the two groups, particularly between the managers of their respective Italian subsidiaries.

In their appeal against the decision, Roche and Novartis argued that the restrictions on the off-label use of Avastin were the result of the decision of the Italian regulatory authority and were not caused by an illegal agreement. The evaluations carried out by the Italian and EU regulatory authorities indicated that Lucentis and Avastin are not equivalent for the purpose of treating eye disease. Roche and Novartis also argued that the systematic off-label use of drugs is unlawful, particularly in a situation where a drug has been approved for the same therapeutic indication. In short, it would have been unlawful to sell Avastin for the eye treatment under the relevant regulatory rules. The Lazio Regional Court rejected these arguments and upheld the decision of the competition authority. On further appeal, the Italian Council of State put several questions to the EU Court of Justice.

In its judgment, the Court of Justice first addressed the question of whether Avastin and Lucentis could be viewed as belonging to the same product market – i.e. products for the treatment of eye disease – even though Avastin's marketing authorisation only covered use for cancer and not eye disease. This question was important because the coordination between Roche and Novartis to try to prevent the off-label use of Avastin would only restrict competition if Avastin were in the same market as Lucentis.

In essence, the Court held that whether a product market would include a product being used off-label in that market depended on the effect that any alleged illegality had on substitutability from the standpoint of supply and demand. Whether such off-label use is 'legal' is not determinative, but it may affect the analysis if any illegality has an impact on the supply and demand of the relevant products. For example, the Court noted that, if a pharmaceutical product is manufactured or sold illegally, it may not be viewed as substitutable or interchangeable because, from the standpoint of the manufacturers and distributors, the supply of the product would entail significant legal, economic and technical risks and risk of reputational damage, and, from the standpoint of payors and doctors, any purchase or use of the products would entail a risk to public health.<sup>34</sup>

<sup>34</sup> Roche/Novartis, para. 52.

The Court's approach of focusing on factors of supply and demand, rather than the question of whether an activity is 'legal' under the applicable EU or national regulations, is pragmatic as it will often be uncertain whether the use of a product off-label is 'legal' – i.e. that it complies with all applicable regulatory requirements. Further, a competition authority is not well placed to resolve this question. Indeed, the Court noted that whether the use of a product off-label is legal is not a matter to be determined by the competition authority, but rather by the competent regulatory authority.<sup>35</sup> In short, the judgment allows competition authorities to focus on standard market definition factors of supply and demand, while also obliging them to take into account any relevant decisions or judgments of regulatory authorities concerning the use of the products, to the extent such decisions or judgments have an impact on the structure of supply and demand.<sup>36</sup>

In the specific case at hand, the Court found that neither the off-label prescription of Avastin nor the repackaging of Avastin so that it could be used for intravitreal injection were necessarily illegal, but that the off-label use and repackaging had to comply with certain regulatory rules.<sup>37</sup> The Court determined that there was no evidence in the file to suggest that the conditions under which repackaged and prescribed were unlawful, though this would be a matter that the referring court could verify.

The Court then addressed the issue of whether the concerted campaign by Roche and Novartis to provide information concerning the possibility of adverse reactions resulting from the off-label use of Avastin constituted a restriction 'by object' in violation of Article 101. For the Court, the provision of such information would be a restriction by object if it were misleading, which was a factual matter to be determined by the national court. The Court then explained that, failing compliance with the requirements of completeness and accuracy laid down in the regulation governing regulatory submissions to the EMA, information would be misleading if the purpose of the information was to (i) confuse the European Medicines Agency and the European Commission so that adverse reactions would be mentioned on the marketing authorisation, which would enable the launch of a communications campaign aimed at doctors and patients to exaggerate the risks, and (ii) to emphasise the risks associated with off-label use of Avastin in the context of medical uncertainty on this issue.<sup>38</sup> The Court also noted that, in a case such as this, where

companies that sold competing products engaged in a joint campaign relating to the product of only one of them, this might constitute evidence that the information was disseminated for reasons other than pharmacovigilance.

The Court's standard for what is 'misleading' seems to place undue emphasis on why the companies are providing the information (i.e. their intent), rather than on whether the information provided is objectively incorrect or misleading. This standard thus provides competition authorities with a procedural shortcut, under which they may establish an infringement without having to prove that statements were actually incorrect or misleading. For example, if a competition authority were able to produce an e-mail by any employee showing an intent to overemphasise the risks associated with the off-label use of a medicine, the company could be held to have committed a 'by object' infringement. In that context, a company's only defense would be to try to establish that all information actually provided was complete and accurate, a showing that would be difficult, at best, as the company would be attempting to prove a negative. While it is appropriate to take intent into account in the analysis of whether certain conduct is anticompetitive, to ascribe such a critical role to intent in these cases arguably goes too far.

The Court's guidance on what is 'misleading' information suggests that the context in which the information is made available is critical as it could show an anticompetitive intent. If, as in *Roche/Novartis*, there is evidence that it was part of a campaign to prevent off-label use for commercial rather than pharmacovigilance purposes, it would seem more likely to be viewed as misleading. Other evidence in *Roche/Novartis* also seemed to work against the companies. While they presented scientific evidence concerning the problems with off-label use, it appears that they omitted to mention contradictory evidence. Also, the fact that preventing off-label use would benefit both companies and that they cooperated in the campaign suggested that they had motives that went beyond pharmacovigilance.

## B. Actavis/Concordia

On 3 March 2017, the CMA issued a Statement of Objections provisionally finding that Concordia and Actavis had signed anticompetitive agreements to restrict entry into the hydrocortisone market.<sup>39</sup> The

35 *Roche/Novartis*, para. 60.

36 *Roche/Novartis*, para. 61.

37 *Roche/Novartis*, para. 59.

38 *Roche/Novartis*, para. 92.

39 Competition and Markets Authority, Press Release, *CMA alleges anticompetitive agreements for hydrocortisone tablets* (3 March 2017) (<https://www.gov.uk/government/news/cma-alleges-anti-competitive-agreements-for-hydrocortisone-tablets>).

CMA also maintained that Actavis abused its dominant position by inducing Concordia to delay market entry. Actavis was the only supplier to the UK until 2015, when it bought the branded version of hydrocortisone, which forced the drug to become de-branded and open to generic competition. Although Concordia received the first marketing authorisation for 10 mg hydrocortisone tablets, it did not enter the market shortly thereafter. Instead, the CMA found that from 2013 to 2016 Actavis agreed to supply Concordia with a fixed amount of its own hydrocortisone tablets at a low price, which Concordia could then resell in the UK. These agreements enabled Actavis to continue to charge high prices in the UK. As discussed earlier in this article, the CMA issued a separate Statement of Objections concerning Actavis' excessive pricing of hydrocortisone tablets to the NHS.

## VI. Parallel trade

There were no major competition law developments concerning the parallel trade of pharmaceuticals in the past year. Nonetheless, the overall debate concerning this practice – whereby parallel traders buy pharmaceuticals in lower priced countries for resale in higher-priced markets – has continued, as have individual cases. As the European Commission made clear in its 2003 Communication on parallel imports of pharmaceuticals,<sup>40</sup> the principle of the free movement of goods within the internal market implies that companies should be able to parallel trade pharmaceuticals across national borders. Parallel traders have been pushing the competition authorities to remove restrictions allegedly implemented by pharmaceutical suppliers to hinder this practice. At the same time, however, governments of lower-priced Member States have sought to impose restrictions on parallel trade in order to prevent drug shortages.

The Bulgarian government has been particularly focused on the issue of medicines shortages, and has used its position of holding the presidency of the European Council to shine a light on the harm caused to lower-income markets arising from parallel trade.<sup>41</sup> In parallel, the Bulgarian government also announced

amendments to the country's medicines law to introduce measures to limit exports.<sup>42</sup>

Members of the European Parliament from Bulgaria, Romania and Spain have also raised questions to the European Commission concerning the impact of parallel trade and its link to shortages of medicines.<sup>43</sup> In response to these questions, the Commission has generally taken a lenient line, allowing proportionate measures by Member States to restrict parallel trade: 'Member States may adopt certain restrictions on parallel trade subject to ensuring compliance with the Treaty provisions. It should be noted that some Member States have already taken national measures to prevent shortages of medicines arising from parallel trade.'<sup>44</sup>

In contrast to these efforts to restrict parallel trade and prevent medicines shortages, the association for Europe's parallel trade industry (EAEPC) has continued its long-running legal fight in Spain to remove alleged barriers to parallel trade. Following a victory in the Spanish Supreme Court in March 2016, the EAEPC has now successfully forced the Spanish competition authority to re-open an investigation into the EAEPC's allegations that innovative suppliers have implemented systems of dual pricing in their distribution agreements (with lower prices applied to products reimbursed by the Spanish healthcare system and higher prices applied to exports), thereby illegally hindering parallel trade in violation of the EU and Spanish competition laws.<sup>45</sup> This investigation remains ongoing.

In parallel, the EAEPC is also taking action before the EU Courts in an attempt to force the European Commission to prosecute similar allegations. In particular, with respect to the long-running case against GSK in Spain (now running for more than 20 years), the EAEPC is challenging the Commission's 2014 decision<sup>46</sup> to cease investigating the dual-pricing system notified by Glaxo Wellcome in 1998. The case is now before the EU General Court, which heard oral arguments by the parties in April 2017 and is likely to issue its judgment soon.<sup>47</sup>

While the judgments in the ongoing cases brought by EAEPC remain outstanding, the January 2017 decision of the Spanish competition authority in the separate *Pfizer/Cofares* case indicates that EAEPC may be

40 European Commission, *Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted*, COM(2003) 839 (30 December 2003).

41 See, e.g., Bulgarian Ministry of Health, Conference Agenda, *A Conference on Options to Provide Better Medicines for All* (6 March 2018).

42 Bulgarian Ministry of Health, Press Release, *The Government Approved the Bill on Medicines, Submitted by Minister Ananiev* (13 December 2017).

43 Parliamentary Questions P-001287-18 (1 March 2018), E-000365-18 (24 January 2018), E-003667-17 (1 June 2017), and E-001508/2017 (6 March 2017).

44 Response of the Commission (12 May 2017) to Parliamentary Question E-001508/2017 (6 March 2017).

45 Press Release, Spanish Competition Authority, *The CNMC initiates infringement proceedings against six pharmaceutical laboratories for possible anticompetitive conduct* (21 March 2017).

46 European Commission, Decision, Case AT.36957, *Glaxo Wellcome* (27 May 2014).

47 Case T-574/14, *European Association of Euro-Pharmaceutical Companies v. Commission*.



unlikely to succeed. In that case, the Spanish authority rejected similar allegations of dual pricing by Pfizer, finding that Pfizer had only set a single price, with the other price fixed by Spanish regulations. The authority also went further in noting that Pfizer's distribution structure created efficiencies and benefits for patients by reducing the risks of shortages of medicines in Spain.<sup>48</sup>

## VII. Sector inquiries

### A. France

In November 2017, the French competition authority (FCA) launched a broad inquiry into the healthcare sector. In the decision opening the sector inquiry,<sup>49</sup> the FCA defined the inquiry's general objectives to include gaining a better understanding of the factors that affect pharmaceutical prices in France and developing strategies to re-balance power between various players in the distribution chain in order to encourage pharmaceutical pricing that takes into account both the economic constraints of the sector and public health needs. Specifically, the FCA expressed an interest in evaluating two broad aspects of the healthcare sector:

- *The factors affecting prices along the pharmaceutical distribution chain.* In particular, the inquiry will assess whether any recommendations should be proposed to improve competitive conditions throughout the distribution chain and enhance the role of intermediary distributors. In a previous sector inquiry conducted in 2013, the FCA found that there was a strong imbalance in the negotiation power between pharmaceutical companies and distributors, which resulted in low margins for distributors. The inquiry will also examine ways to expand the competitive conditions at the pharmacy level, including lessening pharmacies' monopoly over pharmaceutical supply to patients, particularly for non-reimbursable medications (e.g. by loosening pharmacy regulations to allow for the creation of pharmacy chains). The inquiry will also examine ways to modernise the role of pharmacies by facilitating the integration of additional services, such as online sales.
- *The regulation of pharmaceutical pricing.* The inquiry will examine the price negotiation process for reimbursable medications between the national price regulation authority and pharmaceutical companies.

In particular, the FCA will assess what criteria are currently being considered in price negotiations (such as the improvement of medical results, the prices charged elsewhere in Europe), what discounts are being achieved, and whether the process should be modified to better integrate aims such as rewarding innovation and fixing prices that resemble those that would be achieved under normal competitive conditions. The inquiry will also investigate hospital purchases of market-priced pharmaceuticals, including hospital bargaining power. The FCA is particularly interested in the negotiation process relating to particularly innovative or expensive medications that are financed through a special mechanism and whose prices the hospitals do not tend to bargain lower than the cap negotiated through the national price regulating authority.

It is anticipated that the FCA will conclude its inquiry and present initial findings in the latter part of 2018.

### B. Austria

Theodor Thanner, the head of the Austrian competition authority has announced to the press that the Authority had begun an inquiry into the healthcare sector during 2017.<sup>50</sup> While the authority has not yet published any details or formal announcement of this inquiry, its the general aim is to assess the current competitive situation and to gain additional transparency with respect to this sector. The national press has reported that Mr. Thanner decried price hikes for pharmaceuticals in Austria as 'the worst sort of speculation,' indicating that the Authority may examine pricing in particular as part of its inquiry.<sup>51</sup>

## VIII. Conclusion

For internal and external legal advisors active in the pharmaceutical sector, the main takeaway from the European case developments is to remain vigilant. While the past year did not yield any cases involving fines in the hundreds of millions or billions, as in other sectors, there continues to be significant activity by payors, consumer associations, competitors and competition authorities, which has led to cases brought against pharmaceutical companies for a wide range variety of conduct. In general, it appears that EU and national

48 Decision, Spanish Competition Authority, *Pfizer/Cofares* (19 January 2017).

49 Decision 17-SOA-01 (20 November 2017).

50 See 'Wettbewerbschüter nehmen Gesundheitsbranche unter die Lupe,' 2 February 2018.

51 Leopold Stefan, 'Kartellwachter: 'worst speculation' on drug prices,' *Der Standard*, 2 February 2018.

competition authorities are broadening the spectrum of conduct that they choose to prosecute as abusive, from greater attention to excessive pricing – at least for off-patent medicines – to aggressive lobbying strategies with national regulatory bodies. Further, on most issues, the EU and national courts have supported the actions of the competition authorities, adopting legal standards that provide them with significant discretion and placing the burden on pharmaceutical companies to defend the legitimacy of their conduct. In this environment, pharmaceutical companies, particularly those

occupying a potentially dominant market position, cannot view compliance purely as a list of particular actions to avoid, but should instead assess their risk in a more holistic fashion, taking into account the competition authorities' increased willingness to expand their reach to new areas where they perceive a potential harm to the consumer or national health systems

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